

REMARKS**Status of the Application**

Claims 1-34 are pending in this application. The claims have been amended herein in accordance with the suggestions made in the Examiner's 101 rejection and objections. Applicant has also amended claims 1, 15, and 25 to recite that the three-dimensional reconstruction of the target element is generated using Tomosynthesis. Tomosynthesis is discussed throughout the application, for example on page 7, lines 23-26. Applicant has further amended claims 5, 18, and 28 to recite that the radiation absorbance projection images are acquired through a range of angles that is limited to only between about 30 and 120 degrees. Support for these amendments can be found throughout the specification. No new matter is added.

Claim Objections

The Examiner objected to claims 26-34 based on certain informalities. In particular, the Examiner states:

In the following format (location of objection; suggestion for correction), the following correction(s) may obviate the objection(s): (claim 26, line 1, "A computer program"; inserting - -computer-readable medium encoded with a- - before "computer program"), (claim 27, line 1, "A computer program"; inserting - -computer-readable medium encoded with a- - before "computer program"), (claim 28, line 1, "A computer program"; inserting - -computer-readable medium encoded with a- - before "computer program"), (claim 29, line 1, "A computer program"; inserting - -computer-readable medium encoded with a- - before "computer program"), (claim 30, line 1, "A computer program"; inserting - -computer-readable medium encoded with a- - before "computer program"), (claim 31, line 1, "A computer program"; inserting - -computer-readable medium encoded with a- - before "computer program"), (claim 32, line 1, "A computer program"; inserting - -computer-readable medium encoded with a- - before "computer program"), (claim 33, line 1, "A computer program"; inserting - -computer-readable medium encoded with a- - before "computer program"), and (claim 34, line 1, "A computer program"; inserting - -computer-readable medium encoded with a- - before "computer program").

The Applicant has made the changes as suggested by the Examiner.

Claim Rejections Under 35 U.S.C. §101

The Examiner has rejected claims 1-14 and 25-34 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory matter. Specifically, the Examiner states:

The claims are directed toward a computer implemented method and medium involving computational data. Though the properties calculated relate to physical properties, the data is none-the-less generated within a computer without a physical manifestation. Thus, these claims do not produce a final result, which meet the standard of being concrete, tangible, and useful.

The claims must be for a practical application of the abstract idea, law of nature, or natural phenomenon. See *Diehr*, 450 U.S. at 187, 209 USPQ at 8 ("application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection") and *Benson*, 409 U.S. at 71, 175 USPQ at 676 (rejecting formula claim because it "has no substantial practical application").

To satisfy section 101 requirements, the claim must be for a practical application of the 101 judicial exception, which can be identified in various ways:

1) The claimed invention "transforms" an article of physical object to a different state or thing.

2) The claimed invention otherwise produces a useful, concrete, and tangible result, based on the factors discussed in MPEP 2106. See also:

<http://www.uspto.gov/web/offices/pac/dapp/o1-a/preognotice/guidelines 101 20051026.pdf>.

The manipulation of data by applying an iterative reconstruction algorithm is performed by the computer implementing programs and is therefore nonstatutory subject matter. Manipulation of data does not include a physical transformation outside of a computer or representation thereof. A process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter, is not deemed to be concrete, tangible, and useful, and is therefore non-statutory.

An example which would make the instant claims statutory would be to include a step of displaying the three-dimensional reconstruction of the target element. Hence, the data would become concrete, tangible, and useful.

The invention of claims 1 to 14, is not, and was not, limited to the manipulation of data on a processor as a key element of claim 1 is the manipulation of a radiation source to acquire

radiation absorbance images of a target. This does not take place in a computer. The radiation absorbance images are then manipulated to create a three-dimensional reconstruction of the target element – a tangible and concrete result. At least a portion of the three-dimensional reconstruction is displayed in the real world. Claims 1 to 14 comply with 35 U.S.C. § 101. Applicants have amended claims 25 to 34 as suggested by the Examiner, and also to include the amendments made to claim 1. Claims 25 to 34 also comply with 35 U.S.C. § 101.

Claim Rejections Under 35 USC §102 Over Tam

The Examiner has rejected claims 1, 2, 5, 15, 18, 25, and 28 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,270,926 (Tam).

Claims 1, 15, and 25

With respect to independent claims 1, 15, and 25, the Examiner states:

Regarding claims 1, 15, and 25, Tam discloses a method, system, and computer readable medium encoded with a computer program for imaging, comprising acquiring radiation absorbance images of a target element by moving a radiation source (fig. 12, via #30) through a limited plurality of angles with a source and detector (fig. 12, and abstract, lines 1-3), and applying an iterative reconstruction algorithm (fig. 9, and col. 5, lines 26-28) to generate a three-dimensional reconstruction of the target element (abstract, lines 1-3), wherein the iterative reconstruction algorithm is applied using cone-beam forward projection (fig. 9, #72) and back projection (fig. 9, #64).

Further, in response to Applicant's previous arguments the Examiner states:

Regarding Tam and Cheng et al. and in response to applicant's arguments, the recitation "tomosynthesis" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone.

Regarding Tam and Cheng et al. applicant further argues that these references fail to disclose movement through a limited plurality of angles. The Examiner disagrees. Tam and Cheng et al. teach moving through 360 degree along only one

plane. Therefore, movement is through a limited plurality of angles as disclosed in Tam and Cheng et al.

Although Applicant disagrees with the Examiner's rejection of claims 1, 15, and 25 over Tam, Applicant has nevertheless amended independent claims 1, 15, and 25 to recite an imaging method, an imaging system, and a computer-readable medium, respectively, which each apply an iterative reconstruction algorithm to generate a three-dimensional reconstruction of a target element using Tomosynthesis. Tomosynthesis is a manner of imaging that involves small number images (typically 7 to 31) taken from different angles, and from which a large number of "slices" of the imaged object can be generated (typically 30 to 100). Computed Tomography, on the other hand, is an imaging process that requires a large number of images must be taken from 360 degrees around the object to be imaged as each image typically yields data only for one focus plane. Tam relates exclusively to improving conventional Computed Tomography or CT systems by applying computations to make up for missing data during image reconstruction. Tam does not teach or even suggest a method, system, or medium using Tomosynthesis.

In addition, Tam is not moved through *only a limited* plurality of angles as claims 1, 15, and 25 require, but instead is expressly moved through *all* possible angles (like all CT systems), as admitted by the Examiner. Contrary to the Examiner's assertion, it is not possible for Tam's system to move through a limited number of angles while simultaneously moving through all 360 degrees. For these reasons, claims 1, 15, and 25 distinguish over Tam and represent allowable subject matter.

Claims 2, 5, 18, and 28

With respect to claims 2, 5, 18, and 28, the Examiner states:

Regarding claim 2, Tam further discloses wherein the radiation absorbance images are acquired by transmitting x-ray energy from an x-ray source (fig. 12, #22) through the target element (fig. 12, #20) to an x-ray detector (fig. 12, #24).

Regarding claims 5, 18, and 28, Tam further discloses wherein radiation absorbance images are acquired through a range of angles that is between about 30 and 120 degrees (fig. 12, #30).

In response to Applicant's previous arguments, the Examiner states:

Regarding claims 5, 18, and 28, applicant argues that Tam fails to disclose a range of angles between about 30 and 120 degrees. The examiner disagrees. The 360-degree rotation of Tam would necessarily include a range of angles between about 30 and 120 degrees. Therefore, Tam would necessarily read on these claims as recited.

Applicant submits that these claims are not anticipated by Tam at least because Tam does not disclose Tomosynthesis as required by independent claims 1, 15, and 25 upon which these claims depend. In addition, in response to the Examiner's assertion that the 360 degree rotation of Tam would necessarily include a range of angles between 30 and 120 degrees, Applicant has amended claims 5, 18, and 28 to recite that the radiation absorbance projection images are acquired through a range of angles that is *limited to only* between about 30 and 120 degrees. By the Examiner's own admission, Tam does not limit the rotation of his source to only between 30 and 120 degrees, but instead requires the source to rotate a full 360 degrees. Thus, claims 5, 18, and 28 independently distinguish over Tam and represent allowable subject matter.

Claim Rejections Under 35 USC §102 Over Cheng

The Examiner has rejected claims 1, 2, 6, 11, 15, 19, 24, 25, 29, and 34 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,909,476 (Cheng).

Claims 1, 15, and 25

With respect to claims 1, 15, and 25, the Examiner states:

Regarding claims 1, 15, and 25, Cheng et al. discloses a method, system, and computer readable medium encoded with a computer program for imaging, comprising acquiring radiation absorbance images of a target element by moving a radiation source (fig. 5, via the trajectory of S(s)) through a limited plurality of angles with a source and detector (fig. 5), and applying an iterative reconstruction algorithm (title) to generate a three-dimensional reconstruction (col. 3, line 35) of the target element (abstract, lines 1-3), wherein the iterative reconstruction algorithm (col. 6, line 27) is applied using cone-beam forward projection (fig. 4, #406) and back projection (fig. 4, #407).

Further, in response to Applicant's previous arguments the Examiner states:

Regarding Tam and Cheng et al. and in response to applicant's arguments, the recitation "tomosynthesis" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone.

Regarding Tam and Cheng et al. applicant further argues that these references fail to disclose movement through a limited plurality of angles. The Examiner disagrees. Tam and Cheng et al. teach moving through 360 degree along only one plane. Therefore, movement is through a limited plurality of angles as disclosed in Tam and Cheng et al.

As discussed above with respect to Tam, independent claims 1, 15, and 25 have been amended to recite an imaging method, an imaging system, and a computer-readable medium, respectively, which each apply an iterative reconstruction algorithm to generate a three-dimensional reconstruction of a target element using Tomosynthesis. Cheng does not teach or even suggest a method, system, or medium which uses Tomosynthesis. Instead, Cheng teaches a microscope which uses cone-beam tomography.

In addition, as can be seen in Figure 1 of Cheng and the description thereof, the X-ray source of Cheng is not moved through a limited plurality of angles as required by claims 1, 15, and 25. The X-ray source remains still during imaging while the specimen, which is mounted on a mechanical stage, can be rotated relative to the source. (See column 3, lines 27-31.) The Examiner points to Figure 5 of Cheng and the "trajectory of S(s)" as indicating that Cheng's source moves through a plurality of angles. Figure 5, however, is an illustration of a mathematical calculation only, namely the "reprojection" step, and does not represent what is physically occurring during imaging. (See column 7, lines 35-38). Further, the quantity S(s) is not defined at all in the specification, much less as representing the X-ray source. Thus, Cheng does not disclose the use of Tomosynthesis or moving a radiation source through a limited plurality of angles. Accordingly, claims 1, 15, and 25 distinguish over Cheng and represent allowable subject matter.

Claims 2, 6, 11, 19, 24, 29, and 34

With respect to claims 2, 6, 11, 19, 24, 29, and 34, the Examiner states:

Regarding claim 2, Cheng et al. further discloses wherein the radiation absorbance images are acquired by transmitting x-ray energy from an x-ray source (col. 3, lines 25-26) through the target element (fig. 1, #103) to an x-ray detector (fig. 1, #106).

Regarding claims 6, 11, 19, 24, 29, and 34, Cheng et al. further discloses wherein the iterative reconstruction algorithm is necessarily a maximum likelihood algorithm implemented using an expectation-maximization algorithm (col. 8, lines 20-37).

Claims 2, 6, 11, 19, 24, 29, and 34 all depend from independent claims involving a method, system, or medium using Tomosynthesis. As discussed above, Cheng does not relate to Tomosynthesis. Therefore claims 2, 6, 11, 19, 24, 29, and 34 are allowable at least because they depend from allowable base claims.

Claim Rejections under 35 USC §103 over Tam in view of Malamud

The Examiner has rejected claims 3, 7, 16, 20, 26, and 30 under 35 U.S.C. 103(a) as being unpatentable over Tam as applied to claims 2, 15, and 25, and further in view of U.S. Patent No. 6,483,890 (Malamud).

Claims 3, 16, and 26

With respect to claims 3, 16, and 26, the Examiner states:

Regarding claims 3, 16, and 26, Tam discloses a method, system, and medium as recited above.

However, Tam fails to disclose wherein an x-ray detector is a digital x-ray detector having a plurality of detector pixels.

Malamud teaches wherein an x-ray detector is a digital x-ray detector (col. 1, lines 15-24) having a plurality of detector pixels (fig. 2, #16).

It would have been obvious, to one having ordinary skill in the art at the time the invention was made, to modify the method, system, and medium of Tam with the detector of Malamud, since one would have been motivated to make such a modification for more easily processing signals with a computer (col. 1, lines 15-24) as implied from Malamud.

Applicant submits that these claims are not obvious at least because Tam does not disclose Tomosynthesis, as required by independent claims 1, 15, and 25 upon which these

claims depend. This also renders these claims non-obvious over the combination of Tam and Malamud as Malamud does not remedy the deficiencies of Tam. Tam teaches a method of improving Computerized Tomography and does not each or suggest a system involving Tomosynthesis. Thus, claims 3, 16, and 26 are non-obvious over Tam and any combinations involving Tam.

Claims 7, 20, and 30

With respect to claims 7, 20, and 30, the Examiner states:

Regarding claims 7, 20 and 30, Tam further discloses wherein the three-dimensional reconstruction of the target element would necessarily be represented as an array of voxels having a uniform or non-uniform size in three-dimensions, which are characteristic of 3D CT images (abstract, line 2).

In response to Applicant's arguments, the Examiner states:

Regarding claims 7, 20, and 30, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "voxel based reconstruction") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

Contrary to the Examiner's assertions, the Applicant is not relying upon language which is not within the claims. The Applicant is relying upon the language in claims 7, 20, and 30 which recites that the target element is represented as an array of voxels having a uniform or non-uniform size in three-dimensions. There is no teaching or suggestion in Tam which discloses a target element represented as an array of voxels. Instead, Tam discloses a method of reconstructing a three-dimensional image slice by slice using two-dimensional projection images in the plane of the slice. [See, e.g., column 10, lines 32-43.] These two-dimensional slices may then be reconstructed into a three-dimensional image. There is nothing in Tam to indicate the use of voxels. The Examiner points to line 2 of the Abstract of Tam as disclosing claims 7, 20, and 30. The Applicant disagrees. Line 2 of the Abstract simply says that Tam discloses a method and apparatus for reconstructing three-dimensional Computerized Tomography (CT) images. Line 2 of the Abstract says nothing

to indicate that arrays of voxels are being used or are characteristic of three-dimensional CT images. Thus, there is an independent basis for the non-obviousness of these claims over Tam. In addition, claims 7, 20, and 30 are allowable at least because they depend from allowable base claims.

Claim Rejections under 35 USC §103 over Cheng in view of Malamud

The Examiner has rejected claims 3, 7-10, 16, 20-23, 26, and 30-33 under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. as applied to claims 2, 15, and 25, and further in view of Malamud. Specifically, the Examiner states:

Claims 3, 16, and 26

Regarding claims 3, 16, and 26, Cheng et al. discloses a method, system, and medium as recited above.

However, Cheng et al. fails to disclose wherein an x-ray detector is a digital x-ray detector having a plurality of detector pixels.

Malamud teaches wherein an x-ray detector is a digital x-ray detector (col. 1, lines 15-24) having a plurality of detector pixels (fig. 2, #16).

It would have been obvious, to one having ordinary skill in the art at the time the invention was made, to modify the method, system, and medium of Cheng et al. with the detector of Malamud, since one would have been motivated to make such a modification for more easily processing signals with a computer (col. 1, lines 15-24) as implied from Malamud.

Claims 7, 20, and 30

Regarding claims 7, 20, and 30, Cheng et al. further discloses wherein the three-dimensional reconstruction of the target element is represented as an array of voxels having a uniform or non-uniform size in three-dimensions (fig. 2).

Claims 8, 21, and 31

Regarding claims 8, 21, and 31, Cheng et al. further discloses wherein a forward projection step is implemented by ray tracing from the x-ray source to a detector pixel and the forward projection of the target element is obtained by necessarily repeating the ray tracing for each detector pixel to calculate an attenuation value for each voxel in order to reproject the volume (col. 7, lines 7-10).

Claims 9, 10, 22, 23, 32, and 33

Regarding claims 9, 10, 22, 23, 32, and 33, Cheng et al. further discloses wherein a back projection step is implemented by necessarily locating detector pixels containing attenuation information relating to a selected voxel and using those pixels to update the attenuation value of the selected voxel, and wherein the back projection step includes performing a back projection for at least each voxel corresponding to a three-dimensional reconstruction of the target element (col. 7, lines 11-21).

Applicant submits that these claims are not obvious at least because Cheng does not disclose Tomosynthesis, as required by independent claims 1, 15, and 25 upon which these claims depend. This also renders these claims non-obvious over the combination of Cheng and Malamud as Malamud does not remedy the deficiencies of Cheng. Cheng teaches a microscope which uses cone-beam tomography and does not teach or suggest a system involving Tomosynthesis. Thus, claims 3, 7-10, 16, 20-23, 26, and 30-33 are non-obvious over Cheng and any combinations involving Cheng.

Claim Rejections under 35 USC §103 over Tam

The Examiner has rejected claims 4, 14, 17, and 27 under 35 U.S.C. 103(a) as being unpatentable over Tam as applied to claims 1, 15, and 25. Specifically, the Examiner states:

Claims 4, 17, and 27

Regarding claims 4, 17, and 27, Tam discloses a method, system, and medium as recited above. Tam further discloses wherein radiation absorbance images are acquired through a number of angles less than a number (col. 2, lines 56-64).

However, Tam fails to disclose a number of angles less than or equal to about 100.

It would have been obvious, to one having ordinary skill in the art at the time the invention was made, to modify the method, system, and medium of Tam with the above number of angles, since where the general conditions of a claim are disclosed in the prior art, discovering the working ranges involves only routine skill in the art. One would have been motivated to make such a modification to speed up imaging (col. 1, lines 45-46) as implied from Tam.

In response to Applicant's arguments, the Examiner states:

Regarding claims 4, 17, and 27, applicant argues that it would not have been obvious to reduce a number of angles or images since resolution would be reduced. The examiner disagrees with this assessment. Although reducing the number of angles or images may reduce resolution, such an obvious modification would also speed up processing, which is desirable. Therefore, it would have been obvious to have a number of angles that is less than or equal to about 100.

Claims 4, 17, and 27 are not obvious over Tam at least because Tam does not disclose Tomosynthesis as required by independent claims 1, 15, and 25 upon which these claims depend. In addition, the Examiner's assertion that reducing the number of angles would be obvious and would decrease processing time is incorrect. Tam's method of calculation is fundamentally based on acquiring cone-beam projection image data over 360 degrees in a plane to enable convergence of the Radon planar integrals. If the number of images and/or the number of angles are reduced, the processing time for Tam's reconstruction would increase greatly, perhaps to infinity, because the planar integrals and their transforms would take much longer to meet the convergence criterion due to the missing image data. It would be detrimental and perhaps fatal to Tam's methods to reduce the number of angles or images and it would therefore not be obvious to do so. Accordingly, claims 4, 17, and 27 have an independent basis of non-obviousness over Tam.

Claim 14

Regarding claim 14, Tam discloses a method as recited above. Tam further discloses a number of iterations (fig. 9, via #70).

However, Tam fails to disclose a number of iterations less than or equal to about 10.

It would have been obvious, to one having ordinary skill in the art at the time the invention was made, to modify the method of Tam with the above number of iterations, since where the general conditions of a claim are disclosed in the prior art, discovering the working ranges involves only routine skill in the art. One would have been motivated to make such a modification to speed up processing.

Claim 14 is not obvious over Tam at least because Tam does not disclose Tomosynthesis as required by independent claim 1, upon which this claim depends. In addition, Tam never suggests that convergence of the calculations will be immediate or almost immediate and never gives any indication of the number of iterations required for

convergence. Element 70 in Figure 9 of Tam is nothing more than a test that is repeated throughout repetitions of the iterative loop until a convergence test is met [column 8, lines 45 to 56], and it suggests nothing concerning the number of iterations required. In fact, other prior art teaches away from the ability of Tam's algorithm to converge in a small number of iterations. For example, Cheng notes of Tam that "Projection data are corrected by a priori information on the object support, upper and lower bounds of projection values, and reprojected to calculate the missing data. These steps are repeated until some convergence criterion is satisfied. *However, the convergence and optimality of this iterative algorithm have not been established.*" [Cheng, column 2, lines 7 to 17.] It is well known in the art that if "convergence and optimality" of a numerical calculation have not been established, the number of iterations required to perform the calculation may be many times greater than 10. Thus is provided an independent basis for the non-obviousness of claim 14 over Tam.

Claim Rejections under 35 USC §103 over Tam in view of Ning

The Examiner has rejected claims 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over Tam as applied to claim 1, and further in view of U.S. Patent No. 6,480,565 (Ning). Specifically, the Examiner states:

Tam discloses a method as recited above.

However, Tam fails to disclose wherein a target element is at least a portion of a human patient, and wherein the target element is a breast of a female patient.

Ning teaches wherein a target element is at least a portion of a human patient, and wherein the target element is a breast of a female patient (title and cover page).

It would have been obvious, to one having ordinary skill in the art at the time the invention was made, to modify the method of Tam with the breast target of Ning, since one would have been motivated to make such a modification for more accurate detection of breast cancer (col. 3, lines 1-3) as implied from Ning.

Applicant submits that claims 12 and 13 are not obvious at least because Tam does not disclose Tomosynthesis, as required by independent claim 1, upon which these claims depend. This also renders these claims non-obvious over the combination of Tam and Ning as Ning does not remedy the deficiencies of Tam. Tam teaches a method of

improving Computerized Tomography and does not teach or suggest a system involving Tomosynthesis. Thus, claims 12 and 13 are non-obvious over Tam and any combinations involving Tam.

CONCLUSION

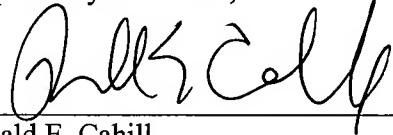
If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 102282-15.

Dated: May 17, 2007

Respectfully submitted,

By 

Ronald E. Cahill

Registration No.: 38,403

NUTTER MCCLENNEN & FISH LLP

World Trade Center West

155 Seaport Boulevard

Boston, Massachusetts 02210-2604

(617) 439-2782

(617) 310-9782 (Fax)

Attorney for Applicant